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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,717	07/25/2003	Scott E. Andersen	38-21(15878)D	2211

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Lawrence M. Lavin, Jr.
Monsanto Company
800 N. Lindbergh Blvd., Mailzone E2NA
St. Louis, MO 63167

EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,717	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *08 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-8 are pending in the instant application. The amendment filed 8/8/2007 has been entered. It is noted that in the previous office action, the examiner had construed the claims, for example claim 1, to read on sequences that were 90-100% identical over the full length of SEQ ID NO: 11. However, the response's reliance on a sequence which has 99% identity to a portion of SEQ ID NO: 11 (66% identity over the full length) (see for example page 7, first para, of the response dated 8/8/2007) indicates that applicants do not agree with this narrow reading. Accordingly, prosecution has been reopened to include rejections under 35 USC 102, to address the breadth of the nucleic acids encompassed by the claims. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is NON-FINAL.

2. In view of the appeal brief filed on 8/8/2007, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have

been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

/Ram R. Shukla/
Supervisory Patent Examiner, AU 1634

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 101

4. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to a substantially purified nucleic acid molecule comprising a sequence having between 90%, 95% and 100% sequence identity with SEQ ID NO: 11 (claims 1-4) as well as consisting of a nucleotide sequence of SEQ ID NO: 11 (claim 5). The claims are also drawn to a substantially purified nucleic acid molecule comprising (claim 6) or consisting (claim 7) of a fragment of about 50 to about 100 residues wherein the fragment exhibits complete complementary to a sequence of SEQ ID NO: 11, the complements thereof, as well as such molecules which comprises a region having a single nucleotide polymorphism (claim 8). Claims 3 and 5 do not allow for internal variations within SEQ ID NO: 11. Claim 3 encompasses putative genes, full open reading frames, fusion constructs and cDNAs. Claims 1-

2, 4, 6, and 8 allow for internal variations. Such claims further encompass mutants, variants, and homologs from any plant or any wheat plant (claim 2), of these genes, full open reading frames, fusion constructs and cDNAs.

The specification teaches that the claimed nucleic acid is an EST isolated from a wheat cDNA library. The claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any EST. The specification discloses many potential uses for the polynucleotide including use as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (page 13), to determine if genes are members of a particular gene family, to obtain full length genes (page 14), to isolate promoters and flanking sequences (page 32), for use in marker assisted breeding programs, to hybridize to its complement, to encode proteins, to obtain molecules from other plants (page 30), and to determine whether a plant contains a mutation (page 32). These are non-specific uses that are applicable to in general to polynucleotides isolated from wheat and not particular or specific to the polynucleotide claimed.

Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. For example, the specification teaches that the claimed nucleic acids can be used to identify a polymorphism. However, this is not considered to be a specific and substantial utility. The utility is not specific because it is a property of all wheat plant nucleic acids that they could be used to search for and try to identify a polymorphism. Further, the asserted utility is not

substantial because it is a utility that is performed only to accomplish additional research. All discussions regarding polymorphisms in the specification are generic in nature. The specification does not teach any particular polymorphisms in SEQ ID NO: 11. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. The specification provides no indication as to what the nucleic acids are markers for. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 11 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of wheat plant. Therefore, the nucleic acids of SEQ ID NO: 11 may only be used to search for polymorphisms and if such polymorphisms are identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined. The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 11 or a protein encoded by SEQ ID NO: 11. SEQ ID NO: 11 may be a portion of a full length open reading frame, but the specification does not teach which protein is actually encoded by SEQ ID NO: 11. For example, it is not clear if nucleotide number 1 is the first nucleotide in a codon, or the last. The specification does not teach an association between the claimed nucleic acids and any particular

condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of an mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids.

Likewise, none of the potential promoters, flanking sequences, mutations, or genes that are to be identified as final products resulting from processes involving the claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, flanking sequences, mutations, and genes does not constitute a specific and substantial utility.

Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the claimed polynucleotides such that another non-asserted utility would be well established for the compounds.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966) and *In re Fisher*, 76 USPQ2d 1225 (CAFC 2005). In *Brenner v. Manson*, the court held that 35 U.S.C. 101 requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that :

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion."

In Fisher, the court held that Fisher's asserted uses for ESTs did not qualify as either specific or substantial utilities under *Brenner v. Manson*.

Claim Rejections - 35 USC § 112

5. Claims 1-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

6. The response traverses the rejections under 35 USC 101 and 112/first paragraph enablement for the same reasons. The response asserts that one use of the elected SEQ ID NO: 11 can be shown by a BLASTN analysis, which is a well-known and conventional technique that can be used to obtain information on nucleic acid sequences and cites the specification at page 5, lines 19-28. This argument has been thoroughly reviewed but was not found persuasive. Although the specification at page 5, explains how a BLASTN search is performed, the specification provides no specific or substantial utility for SEQ ID NO: 11. Any nucleic acid sequence, including any sequence from a wheat plant, can be used in a BLAST analysis. Such use in therefore not specific. This utility is not substantial because no substantial utility is set forth in the specification regarding any particular sequence obtained using BLAST analysis with SEQ ID NO: 11, nor what the specific and substantial utility of that sequence would be. The specification merely discloses that the skilled artisan may perform a BLASTN search on the sequences disclosed to then determine if a specific and substantial utility exist for the sequences in the specification. This is not a specific and substantial utility but rather an invitation for the artisan to then determine whether a specific and substantial utility exists.

In the instant situation, the response references a search which showed 99% identity to a storage protein sequence obtained from Triticum aestivum and asserts that the sequence was obtained by Kawaura et al; Plant Physiol, vol. 139, pages 1870-1880, 2005. It is noted, however, that no alignment is provided nor does the response provide what database this alignment is obtained from, nor which sequence from Kawaura this corresponds to. Additionally, it is noted that SEQ ID NO: 11 is 392 nucleotides long, however the search indicates a score of identities of 259 out of 260. Accordingly it appears that the asserted 99% is only to a portion of SEQ ID NO: 11. Further, the response fails to provide what portion of SEQ ID NO: 11 was responsible for this observed identity, nor does the specification provide any guidance whatsoever as to which portions from within SEQ ID NO: 11 should be searched, again leaving it to the artisan to determine for themselves, what information may be gleaned from the disclosed sequence. Regardless of such, however, it is noted that the instant application effective priority date is 6/15/2000 and the filing date of the instant application is 7/25/2003, while the paper cited was published in 2005. The specification at the time the invention was filed only generally discloses that the SEQ ID NOS can have high homology to wheat proteins but does not teach what these wheat proteins are, how they function, or whether any homology less than 100% identity would provide for a predictable correlation between the structure and function of the putative unknown, undisclosed homologue. However, In *Brenner v. Manson*, the court held that : "...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion." Here, the specification does not teach homology to storage proteins, nor what the utility of a storage protein is or whether all storage proteins have the same structure and function or whether less than 100% identity to a storage protein would predictably determine

what the specific function of that protein was. The reference cited in the response was published after the instant invention was filed and does not provide for a well established utility for SEQ ID NO: 11 at the time of the invention. Accordingly, the response's reference to *In re Fisher*, and *Raytheon Co. v. Roper Corp* are not persuasive to overcome the rejection. If applicants are relying on the fact that BLAST analysis can identify homologues, it is noted that the claims are not directed to methods of BLAST analysis but rather to a nucleic acid molecule for which the specification teaches no substantial utility. The specification provides no teaching of any immediate benefit to the public regarding the sequence of SEQ ID NO: 11. The fact that the citation applicants are relying on is after the filing date of the invention illustrates that no immediate benefit has been disclosed by the specification at the time the invention was filed nor was it well established in the art at the time the invention was filed.

The response questions the examiner's parameters used to determine that the storage protein encoding sequence is 99% identical to only a portion of (66%) of SEQ ID NO: 11. In response, applicants are directed to page 6 of their response filed 11/3/2006 where the results of the search analysis indicate an identity of 259 out of 260. As SEQ ID NO: 11 is 392 nucleotides long, 259 identical nucleotides out of a total of 392 nucleotides is 66%. If it the % identity is higher, the response dated 11/3/2006 provides no indication or alignment as to which portions of the 392 nucleotides of SEQ ID NO: 11 have "99% identity" to SEQ ID NO: 11. The response's assertions that the fact that 66% of SEQ ID NO: 11 is 99% identical to a storage protein obtained from Triticum aestivum is substantial and credible because the nucleic acid molecules of the present invention can be use to isolate genes, map genes, and determine gene function associated with protein storage is not found persuasive. Again, as set forth above, none of this information

was known to the skilled artisan at the time the invention was filed, either by disclosure in the specification or a well established utility in the prior art. The citation of the website at page 6 of the response is also not persuasive as it does not provide any indication that the specification, at the time of filing provided any guidance as to any of the sequences being homologous to a storage protein. The response's references to In re Oetiker, and the 2001 Utility guidelines is also not found persuasive. It is specifically noted that the patent application provides absolutely no disclosure or assertion of a specific, substantial, or credible utility based upon homology to an existing nucleic acid or protein having an accepted utility. The homology analysis relied on by applicants is to a sequence taught in the prior art after the instant application was filed.

The response's assertion with regard to "reasonable correlation" has been thoroughly reviewed but was not found persuasive. In *Fujikawa v. Wattanasin*, the issue referenced in the response related to reasonable correlation between in vitro and in vivo pharmacological activity of a compound. However, in the instant application, the specification fails to disclose any in vitro or in vivo activity for SEQ ID NO: 11 or a protein, if one exists, encoded by SEQ ID NO: 11. The argument that BLASTN analysis provides reasonable correlation is not found persuasive. It is not clear or apparent what reasonable correlation is determined from 99% identity over only a portion of SEQ ID NO: 11 (66%) with a sequence determined after the filing date of the instant application, nor is such taught in the specification.

Regarding the response's assertion that the examiner has not met the burden of establishing that the instantly claimed nucleic acid is not supported by a specific or substantial utility, applicants are directed to the rejection set forth above, which is in accordance with the ruling in *In re Fisher*. The fact that applicants are attempting to establish a specific and

substantial utility that was not disclosed or known in the art at the time the invention was filed does not overcome the fact that the instant specification is silent with regard to an asserted real world utility for the claimed sequence. With regard to the response's assertion that the examiner has provided no proof that the Kawaura et al sequence is an EST, applicants are directed to the Kawaura et al reference which is directed to EST sequences (see Title, "Results" etc). Further, the response's assertion that knowledge of the homology of SEQ ID NO: 11 can be used in a manner that provides some immediate benefit to the public is not found persuasive. First, the specification does not provide any such disclosure nor was it known at the time the invention was filed. Second, Kawaura et al does not teach how to use SEQ ID NO 11 to develop plants with enhanced protein storage ability.

The rejections are therefore maintained.

7. Claims 1-4, 6, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a substantially purified nucleic acid molecule comprising a sequence having between 90%, 95% and 100% sequence identity with SEQ ID NO: 11 (claims 1-4). The claims are also drawn to a substantially purified nucleic acid molecule comprising (claim 6) a fragment of about 50 to about 100 residues wherein the fragment exhibits complete complementary to a sequence of SEQ ID NO: 11, complements thereof, as well as such

molecules which comprises a region having a single nucleotide polymorphism (claim 8). Claim 3 does not allow for internal variations within SEQ ID NO: 11. However, SEQ ID NO: 11 does not appear to be a full length open reading frame and therefore, claim 3 encompasses putative genes, full open reading frames, fusion constructs and cDNAs. Claims 1-2, 4, 6 and 8 allow for internal variations within SEQ ID NO: 11, as well as requiring that only partial sequences from within SEQ ID NO: 11 be included in the encompassed nucleic acid molecules. In other words, claim 1, for example, does not require that the %identity be over the full length of SEQ ID NO: 11, and therefore encompasses sequences which only have 90-100% to any small portion of SEQ ID NO: 11. Such claims encompass mutants, variants, and homologs, as well as functionally unrelated molecules from any plant or any wheat plant (claim 2), of these genes, full open reading frames, fusion constructs and cDNAs. Further, because the specification is silent with regard to the function of SEQ ID NO: 11, the skilled artisan would not be able to determine whether a sequence was a homolog with similar function or whether the molecule was functionally unrelated to SEQ ID NO:11.

The specification teaches the sequence of SEQ ID NO: 11. SEQ ID NO: 11, per se, meets the written description requirement of 35 USC 112, first paragraph. However, SEQ ID NO: 11 is an EST, and is less than a full length open reading frame. It appears to be a fragment of a larger protein since it was isolated from a Triticum aestivum cDNA library. However, the specification does not teach the function of the larger protein encoded by SEQ ID NO: 11, and provides no description of the remainder of the coding sequence of which SEQ ID NO: 11 appears to be a part of. It is not clear what peptide is encoded by SEQ ID NO: 11, as the specification does not teach, for example, if nucleotide position #1 of SEQ ID NO: 11 is the first

nucleotide in a codon, or the second or third. Accordingly, it is not even clear that SEQ ID NO: 11 encodes a protein (claim 2). Further, claim 2 specifically recites a nucleic acid which encodes a wheat protein, or fragment of a wheat protein. However, the specification does not teach what structural requirements of the genus of nucleic acids of claim 1 make a sequence a wheat protein vs that of another plant, or organism. It is not clear which structural aspects of SEQ ID NO: 11, distinguish it from "non wheat" proteins. Accordingly, it is not representative of the genus of sequences encompassed by the claims. Further, claims 1, 2, 4, 6, and 8 encompass sequences which possess variations with regard to the sequence of SEQ ID NO: 1, while claims 1-4, 6, and 8, due to the language "comprising" encompass a large genus of sequences which are larger than SEQ ID NO: 11. Although, for example, claim 3 encompasses a vector which comprises SEQ ID NO: 11, the claim also encompasses a full length cDNA, as well as genomic sequences, which have not been described by the specification. Such sequences include introns, exons, promoters, enhancers, 5' and 3' UTR's, all of which have not been described by the specification. Further, claims 1, 2, 4, 6, and 8 encompass allelic variants, mutants, and homologs of the undisclosed cDNA and genomic sequences. As such, each member of the claimed genus does not contain the same structural feature. This represent a large variable genus of nucleic acid molecules which are not represented by the single sequence of SEQ ID NO: 11. The specification does not disclose a single variant or homolog of SEQ ID NO: 11, nor any sequence with a "single nucleotide polymorphism". There is no structure function correlation between the single disclosed species, and the large genus of genes, cDNAs, mutants, variants, and homologs encompassed by the broadly claimed invention.

Beyond providing the sequence data for SEQ ID NO: 1 1, however, the specification provides no teaching or guidance which correlates the sequence of SEQ ID NO: 11 to its function, which amino acids in the protein encoded by SEQ ID NO: 11 are critical to its function, or how to modify SEQ ID NO: 11 to obtain any specific homolog, mutant, or variant. It is not clear which positions with SEQ ID NO: 11 can be substituted or altered without resulting in a loss of the function of SEQ ID NO: 11 . Therefore, the skilled artisan would be unable to determine whether or not a DNA molecule is functionally equivalent to SEQ ID NO: 11.

While one could argue that the claimed genus of polynucleotides is adequately described since one can identify these polynucleotides by sequence comparison using the polypeptide/polynucleotide structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone is not a reliable indicator of a protein's function. For example, Skolnick (Skolnick and Fetrow, TIBTECH, January 2000, vol. 18, pp 34-39) teaches (p. 35, "Box 1") that a common protein characteristic that makes functional analysis based only on homology especially difficult is the tendency of proteins to be multifunctional. Skolnick teaches that for example, lactate dehydrogenase binds NAD, substrate, and zinc and performs a redox reaction and that each of these occurs at different functional sites that are in close proximity and the combination of all four sites creates the fully functional proteins. Skolnick teaches that because the sequence identity between subfamilies is so high, standard sequence similarity methods could easily misclassify new sequences as members of the wrong subfamily if the functional sites are not carefully considered.

The genus of polynucleotides comprised by the claims is a large variable genus, which can potentially encode proteins of diverse functions. The specification only discloses a single

species of the genus, i.e. the polynucleotide of SEQ ID NO: 11, which is insufficient to put one of skill in the art in possession of all attributes and features of all species within the genus. The specification fails to teach any other relevant identifying characteristics which would identify a sequence as a variant, mutant, or homolog of the genus of possible sequences encompassed by the scope of the claims. For example, with regard to claim 2, the specification is silent as to which nucleotide changes can be made to SEQ ID NO: 11 and still identify it as a wheat protein. Thus one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed with respect to claims 1-4, 6, and 8.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of a substantially purified nucleic acid molecule consisting of the sequence of SEQ ID NO: 11, and the complete complement thereof, the only species disclosed in the specification, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai

Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Response to arguments

8. The response traverses the rejection. The response asserts that the specification demonstrates that applicant was in possession of the claimed genus of nucleic acid molecules when the application was filed and that the applicants have provided a detailed chemical structure of SEQ ID NO: 11. It is further asserted that the fact that the nucleic acids are joined with additional sequences, or variants is beside the point because such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. This argument was thoroughly reviewed but was not found persuasive. The rejection is based on the fact that the claims include full length genomic sequences comprising the recited SEQ ID NO: 11 (claim 3) or a fragment of SEQ ID NO: 11 (claim 6). With regard to claim 2, the

specification provides no description as to attributes which would identify a sequence which shared partial homology to SEQ ID NO 11 as encoding a wheat protein, as opposed to any protein in general. With regard to claims 1 and 4, the claims further encompass sequences having between 90% to 100% identity with SEQ ID NO: 11 and sequences comprising these variant sequences. With regard to claim 8, the claim further encompasses sequences which are polymorphic with respect to SEQ ID NO: 11. Thereby, the claims encompass mutants, allelic variants, splice variants and homologues of SEQ ID NO: 11 which are not adequately described in the present specification. The genus of nucleic acids encompassed by the claims is extremely broad and is not limited to vectors comprising the nucleic acids or to nucleic acids comprising a label. The claims further encompass mutants, allelic variants, splice variants and homologues of SEQ ID NO: 11. A general statement in the specification of a desire to obtain gene sequences, homologues from other species, mutated species, SNPs, polymorphic sequences, promoter sequences and exogenous sequences is not equivalent to providing a clear and complete description of specific sequences which fall within the claimed genus of nucleic acids. As discussed in the rejection, the court in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), held that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". While the specification is not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. In the present situation, the specification has provided only a disclosure of a wish to obtain homologues, mutant, allelic, and

splice variants of SEQ ID NO: 11. The specification does not disclose any specific mutant, allelic, or splice variants or homologues or SPSs of SEQ ID NO: 11. Further, the functional activity of such variants is not disclosed. Accordingly, the specification has not disclosed a representative number of nucleic acid molecules within the claimed genus.

Although the response asserts that applicants have provided a detailed chemical structure, SEQ ID NO: 11, the claims are not limited to nucleic acids which share this common structural feature. Rather, the claims encompass nucleic acids having between 90 and 100% identity with SEQ ID NO: 11. Thereby, the claimed genus of nucleic acids do not share the same common structural feature of containing the sequence of SEQ ID NO: 11. The specification does not disclose what specific sequence information must be shared by the claimed genus of nucleic acid molecules in order to ascertain which nucleic acids share a common structural feature. The genus of molecules having 90-99.9% identity with SEQ ID NO: 11 includes individual species of nucleic acids which may vary from SEQ ID NO: 11 at any given nucleotide position within SEQ ID NO: 11. When the individual species within the genus are compared to one another, together this genus comprises nucleic acids which vary at each and every nucleotide position within SEQ ID NO: 11. Accordingly, the genus of nucleic acids are not considered to share a common structural feature – i.e., there is no specific structural property that is common to all members of the claimed genus if each of the individual nucleotides may be varied. Further, the claims do not recite a functional requirement for any of the claimed nucleic acids and thereby encompass nucleic acids having distinct functional properties.

The response asserts that nucleic acids falling within the scope of the claims are readily identifiable and that one of ordinary skill in the art could identify whether a particular sequence

meets the claimed characteristics or not. However, it is noted that the criteria for meeting the Written Description requirement is not limited to providing a means for distinguishing between molecules which fall within the claimed genus and molecules which fall outside the claimed genus. Rather, the Written Description requirement is met by providing a showing that Applicants were, at the time the application was filed, in possession of the claimed invention. Providing a statement that the invention covers nucleic acid having 90-99.9% identity with SEQ ID NO: 11 is not equivalent to disclosing specific nucleic acids which fall within the claimed genus of nucleic acids. The specification does not disclose a single molecule within the genus of nucleic acids having 90-99.9% identity with SEQ ID NO: 11. The specification does not describe the location or identity of nucleotides which may be varied within SEQ ID NO: 11, and does not describe the functional activity or other biological role associated with such variants. The specification also does not disclose any specific variants of SEQ ID NO: 11 which have a functional activity or biological role distinct from that of SEQ ID NO: 11. Since the function fo the protein encoded by SEQ ID NO: 11 is not disclosed in the specification or the art a the time of filing, the skilled artisan would have no way of knowing or predicting which nucleic acid modification would result in a loss of function vs those that do not. Modification of a nucleic acid sequence by 1 to 10% can significantly alter the functional activity of the nucleic acid and the protein encoded thereby. The genus of nucleic acids claimed is large and variable, and potentially includes nucleic acids encoding for proteins having diverse biological functions. The specification discloses only one member of this genus, i.e., SEQ ID NO: 11. This is not sufficient to place one of skill in the art in possession of a representative number of molecules having the varied attributes and features of species within the claimed genus. Accordingly, it is

maintained that the written description requirements have not been adequately met for the broadly claimed genus of homologues, splice, mutant and polymorphic variants of SEQ ID NO:11. The rejection is therefore maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by EST accession number AW566142 (March 10, 2000).

Accession number AW566142 teaches a nucleic acid molecule which has "a" nucleotide sequence which exhibits 90-100% and 95-100% with portions of SEQ ID NO: 11. The alignment between the AW566142 molecule and SEQ ID NO 11 is set forth below. Numerous contiguous regions of 100% identity between the two molecules are illustrated in the alignment.

```
AW566142
LOCUS       AW566142                562 bp    mRNA    linear   EST 10-MAR-2000
DEFINITION  660062E10.y1 660 - Mixed stages of anther and pollen Zea mays cDNA,
            mRNA sequence.
ACCESSION   AW566142
```

```
VERSION     AW566142.1  GI:7227501
KEYWORDS    EST.
SOURCE      Zea mays
  ORGANISM  Zea mays
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae; PACCAD
            clade; Panicoideae; Andropogoneae; Zea.
REFERENCE   1  (bases 1 to 562)
  AUTHORS   Walbot,V.
  TITLE     Maize ESTs from various cDNA libraries sequenced at Stanford
            University
  JOURNAL   Unpublished (1999)
COMMENT     Contact: Walbot V
            Department of Biological Sciences
            Stanford University
            855 California Ave, Palo Alto, CA 94304, USA
            Tel: 650 723 2227
            Fax: 650 725 8221
            Email: walbot@stanford.edu
            Plate: 660062  row: E  column: 10.

  Query Match             60.1%;  Score 235.4;  DB 7;  Length 562;
  Best Local Similarity   79.7%;  Pred. No. 2.5e-40;
  Matches  307;  Conservative    0;  Mismatches   66;  Indels   12;  Gaps    2

Qy          8 ACCAAGGTGGCCGCCAAGGTCTTCGAGCTCGACCCGGACGGAATGGTGCAGGCGCTGGCC 67
              | || ||| | ||||| |  ||||||| |||||| |||||| |||||| |||||| ||
Db          7 AGCAGGGTCGTCGCCAGGTCCTTCGAGGCCGACCCCGACGGAGTGGTGCGGGCGCTCGCG 66

Qy         68 GCGGTGCTGCGGGACAAGATCACCATGCCCGGCCAGCTCATGACCGACGGCCGCGACGCC 127
              || ||  |||| | |||| |||||||||||||| ||| |||||| |||||||||||| |
Db         67 GCCGTCATGCGAGCCAAGGTCACCATGCCCGGCGAGCGCATGACGGACGGCCGCGACGAC 126

Qy        128 GACTTGTTCGAGCACTTCTCGGCGGTCGCGCAGCGCACCGGGGTGTACACGGCAAGAGAC 187
              | | ||||| |||||||||||||| ||||||||| ||||||||||||||||    |||
Db        127 AGCCTCTTCGACCACTTCTCGGCGGTGGCGCAGCGCGCCGGGGTGTACACGGCGGCGGAC 186

Qy        188 TACGGCGACATGGTGGAGCACTTCGTGCGTAGGTGGAAGGTGGCGGACCTCGGCGGGGGG 247
              |||||||||||||||||||||||||||| | ||||| ||||||||  |||   ||
Db        187 TACGGCGACATGGTGGAGCACTTCGTGCGCACGTGGAGGGTGGCGGGGCTCCAGGG---- 242

Qy        248 CAGCTGTCCGGGGAGGGGCGGCGCGCGCAGGAGTACGTGTGCGGGCTGCCGCGCAAGATC 307
              |||||| || |||||||| |||||||| || ||||||||||||||||||||||||||||
Db        243 --GCTGTCTGGCGAGGGGCGCCGCGCGCAAGACTACGTGTGCGGGCTGCCGCGCAAGATC 300

Qy        308 CGGCGGGTGGAGGAGCTGGCCCACGACCGCGTGATCAAAGCCGCAAAAGAGCCCGAGTTC 367
              ||  || |||||||||||||||||||| |         |||  ||||||| || | |
Db        301 CGCAGGATGGAGGAGCTGGCCCACGACCGTG------CCGCCCAAAAAGAGGCCCAATCT 354

Qy        368 GCAAGGTTCAGCTGGGTCTTCGACA 392
              |  ||  |||||||||| |||||||
Db        355 GTCAGCATCAGCTGGGTGTTCGACA 379
```

11. Claims 1 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by EST accession number AI677542 (Feb 2000, first made available to NCBI May 25, 1999).

Accession number AI677542 teaches a nucleic acid molecule which has "a" nucleotide sequence which exhibits 90-100% and 95-100% with portions of SEQ ID NO: 11. The

alignment between the AI677542 molecule and SEQ ID NO 11 is set forth below. Numerous contiguous regions of 100% identity between the two molecules are illustrated in the alignment.

```
LOCUS       AI677542                552 bp    mRNA    linear   EST 02-FEB-2000
DEFINITION  605056G04.x1 605 - Endosperm cDNA library from Schmidt lab Zea mays
            cDNA, mRNA sequence.
ACCESSION   AI677542
VERSION     AI677542.1  GI:4887443
KEYWORDS    EST.
SOURCE      Zea mays
  ORGANISM  Zea mays
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae; PACCAD
            clade; Panicoideae; Andropogoneae; Zea.
REFERENCE   1  (bases 1 to 552)
  AUTHORS   Walbot,V.
  TITLE     Maize ESTs from various cDNA libraries sequenced at Stanford
            University
  JOURNAL   Unpublished (1999)
COMMENT     Contact: Walbot V
            Department of Biological Sciences
            Stanford University
            855 California Ave, Palo Alto, CA 94304, USA
            Tel: 650 723 2227
            Fax: 650 725 8221
            Email: walbot@stanford.edu
            Plate: 605056  row: G  column: 04.
FEATURES             Location/Qualifiers
     source          1. .552
                     /organism="Zea mays"
                     /mol_type="mRNA"
                     /cultivar="Ohio43"
                     /db_xref="taxon:4577"
                     /tissue_type="nucellar, embryo, and endosperm"
                     /dev_stage="10-14 days post-pollination"
                     /lab_host="DH5(alpha)"
                     /clone_lib="605 - Endosperm cDNA library from Schmidt lab"
                     /note="Organ: Kernel; Vector: pAD-GAL4-2'; Site_1: EcoRI;
                     Site_2: XhoI; Kernel endosperm cDNA library from Schmidt
                     lab"

  Query Match             38.9%;  Score 152.4;  DB 1;  Length 552;
  Best Local Similarity   65.6%;  Pred. No. 1.6e-22;
  Matches  257;  Conservative    0;  Mismatches  126;  Indels    9;  Gaps    2;

Qy          1 GGCCTACACCAAGGTGGCCGCCAAGGTCTTCGAGCTCGACCCGGACGGAATGGTGCAGGC 60
              ||| |||       | |  |   || |  |  |||| ||||||||||    ||||  ||
Db        480 GGCGTACGGGCGCATCGTGGAGCAGCTGCTGCAGCTGGACCCGGACGGCGCCGTGCTCGC 421

Qy         61 GCTGGCCGCGGTGCTGCGGGACAAGATCACCATGCCCGGCCAGCTCATGACCGACGGCCG 120
                | || |   || ||||  |   |||||||||||||  || ||||||  |||||||||
Db        420 CGTCGCGGACATGATGCGCAAGCGGATCACCATGCCCGCGCACCTCATGCACGACGGCCG 361

Qy        121 CGACGCCGACTTGTTCGAGCACTTCTCGGCGGTCGCGCAGCGCACCGGGGTGTACACGGC 180
              ||||   ||| ||||||||||||||| | || ||||| ||||||  ||| ||||||||  ||
Db        360 CGACATGGACCTGTTCGAGCACTTCGCCGCCGTCGCCCAGCGCCTCGGCGTGTACACCGC 301

Qy        181 AAGAGACTACGGCGACATGGTGGAGCACTTCGTGCGTAGGTGGAAGGTGGCGGACCTCGG 240
                | |||||||  ||||| || |||  | | ||     |||||||| ||| |   || |
Db        300 CCGGGACTACGCGGACATCGTCGAGTTCCTTGTCAAGCGGTGGAAGCTGGAGACACTGGA 241

Qy        241 CGGGGGGCAGCTGTCCGGGGAGGGGCGGCGCGCGCAGGAGTACGTGTGCGGGCTGCCGCG 300
                | ||   ||| ||||| ||||| ||  | ||   ||| | ||| ||||||||  |||
Db        240 GAGCGG---GCTCTCCGGCGAGGGCCGCAGGGCCAGGGACTTCGTCTGCGGGCTCGCGCC 184
```

```
Qy        301 CAAGATCCGGCGGGTGGAGGAGCTGGCCCACGACCGCGTGATCAAAGCCGCAAAAGAGCC 360
              | ||| || |||| | |||||  ||| | ||| | |  |  || |      | |||||
Db        183 GAGGATGCGCCGGGCCGCGGAGCGCGCCGAGGACAGGGCCAAGAAGG------ACGAGCC 130

Qy        361 CGAGTTCGCAAGGTTCAGCTGGGTCTTCGACA 392
              |  | | |  | ||||||||||| |||| || |
Db        129 CAGGATGGTCAAGTTCAGCTGGATCTTTGATA 98
```

12. Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Cahoon (Cahoon et al; US Patent 6,762,345).

Cahoon teaches a nucleic acid molecule which has "a" nucleotide sequence which exhibits 90-100% and 95-100% with portions of SEQ ID NO: 11. The alignment between SEQ ID NO 13 taught by Cahoon and SEQ ID NO 11 is set forth below. Numerous contiguous regions of 100% identity between the two molecules are illustrated in the alignment.

```
LOCUS       AR569415               1623 bp    DNA     linear   PAT 14-DEC-2004
DEFINITION  Sequence 13 from patent US 6762345.
ACCESSION   AR569415
VERSION     AR569415.1  GI:56569940
KEYWORDS    .
SOURCE      Unknown.
  ORGANISM  Unknown.
            Unclassified.
REFERENCE   1  (bases 1 to 1623)
  AUTHORS   Cahoon,R.E., Famodu,O.O. and Shen,J.B.J.
  TITLE     Plant stearoyl desaturases
  JOURNAL   Patent: US 6762345-A 13 13-JUL-2004;
            E. I. du Pont de Nemours and Company; Wilmington, DE
FEATURES             Location/Qualifiers
     source          1. .1623
                     /organism="unknown"
                     /mol_type="genomic DNA"


  Query Match             39.2%;  Score 153.8;  DB 2;  Length 1623;
  Best Local Similarity   67.4%;  Pred. No. 9.4e-26;
  Matches  234;  Conservative    0;  Mismatches  107;  Indels    6;  Gaps    1;

Qy          2 GCCTACACCAAGGTGGCCGCCAAGGTCTTCGAGCTCGACCCGGACGGAATGGTGCAGGCG 61
              |||||||||||| | | ||  ||| |||||||| | ||||| ||     |  |||| |||
Db        889 GCCTACACCAAGATAGTCGAGAAGCTCTTCGAGATGGACCCTGATTACACAGTGCTTGCG 948

Qy         62 CTGGCCGCGGTGCTGCGGGACAAGATCACCATGCCCGGCCAGCTCATGACCGACGGCCGC 121
              | || |   || || || | |||||||| |||||| | ||| ||||||  ||||||
Db        949 TTTGCTGACATGATGAGGAAGAAGATCACGATGCCAGCCCATCTCATGTACGACGGTAAG 1008

Qy        122 GACGCCGACTTGTTCGAGCACTTCTCGGCGGTCGCGCAGCGCACCGGGGTGTACACGGCA 181
              |||| | || ||||||||||||||   ||||| ||||||  |    || || ||||| ||
Db       1009 GACGACAACCTGTTCGAGCACTTCAGCGCGGTGGCGCAGAGGCTGGGCGTCTACACCGCC 1068

Qy        182 AGAGACTACGGCGACATGGTGGAGCACTTCGTGCGTAGGTGGAAGGTGGCGGACCTCGGC 241
              | |||||||| ||||||  | |||  | | || |  |||||||| || ||||| |||
Db       1069 AAAGACTACGCCGACATCCTCGAGTTCCTGGTCCAGAGGTGGAAAGTCGCGGAGCTCACA 1128
```

```
Qy       242 GGGGGGCAGCTGTCCGGGGAGGGGCGGCGCGCGCAGGAGTACGTGTGCGGGCTGCCGCGC 301
             ||      |||||| || || ||| |  |||||||||| |  || ||     || |||
Db      1129 GG------GCTGTCTGGAGAAGGGAGAAGCGCGCAGGACTTTGTCTGTACCTTGGCGCCG 1182

Qy       302 AAGATCCGGCGGGTGGAGGAGCTGGCCCACGACCGCGTGATCAAAGC 348
             | |||| ||||| |||| ||    || || |   | | ||   ||||
Db      1183 AGGATCAGGCGGCTGGATGATAGAGCTCAAGCGAGGGCGAAGCAAGC 1229
```

13. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession number AF020203 (1998).

Accession number AF020203 teaches a nucleic acid molecule which has "a" nucleotide sequence which exhibits 90-100% and 95-100% with portions of SEQ ID NO: 11. The alignment between the AF020203 molecule and SEQ ID NO 11 is set forth below. Numerous contiguous regions of 100% identity between the two molecules are illustrated in the alignment.

```
AF020203
LOCUS       AF020203               1001 bp    mRNA    linear  PLN 15-MAY-1998
DEFINITION  Pelargonium x hortorum stearoyl-ACP desaturase (pxh-A) mRNA,
            partial cds.
ACCESSION   AF020203
VERSION     AF020203.1  GI:3133286
KEYWORDS    .
SOURCE      Pelargonium x hortorum
  ORGANISM  Pelargonium x hortorum
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; eudicotyledons; core eudicotyledons;
            rosids; Geraniales; Geraniaceae; Pelargonium.
REFERENCE   1  (bases 1 to 1001)
  AUTHORS   Schultz,D.J., Mumma,R.O., Cox-Foster,D., Craig,R. and Medford,J.I.
  TITLE     Geranium stearoyl-ACP desaturase
  JOURNAL   Unpublished
REFERENCE   2  (bases 1 to 1001)
  AUTHORS   Schultz,D.J., Mumma,R.O., Cox-Foster,D., Craig,R. and Medford,J.I.
  TITLE     Direct Submission
  JOURNAL   Submitted (19-AUG-1997) Botany, MSU, 166 Plant Biology Building,
            East Lansing, MI 48824, USA
FEATURES             Location/Qualifiers
     source          1. .1001
                     /organism="Pelargonium x hortorum"
                     /mol_type="mRNA"
                     /db_xref="taxon:4031"
                     /tissue_type="glandular trichomes"
     gene            <1. .1001
                     /gene="pxh-A"
     CDS             <1. .670
                     /gene="pxh-A"
                     /codon_start=2
                     /product="stearoyl-ACP desaturase"
                     /protein_id="AAC16442.1"
                     /db_xref="GI:3133287"
                     /translation="AEENRHGDLLNKYLYLSGRIDMRQIEKTIQYLIGSGMDPKTENN
                     PYLGFIYTSFQERATFVSHGNTARHAKDHGDLKLAQICGTIAADEKRHETAYTKIVEK
                     LFELDPDGTVMALSDMMRKKISMPAHLMFDGKDDNLFEHFSRSQRLGVYTARDYADIL
```

```
                    EFLVARWNVDKLTGLSGEGRRAQDYVCGLAQRIRRLEERAQKRAKEATMVPFSWIFGR
                    EVLL"

  Query Match             38.0%;  Score 148.8;  DB 4;  Length 1001;
  Best Local Similarity   65.7%;  Pred. No. 1.5e-24;
  Matches  251;  Conservative    0;  Mismatches  122;  Indels    9;  Gaps    2;


Qy          2 GCCTACACCAAGGTGGCCGCCAAGGTCTTCGAGCTCGACCCGGACGGAATGGTGCAGGCG 61
              |||||||||||| | |  |  ||| ||||||||||||||||| ||||| |  ||   ||||
Db        284 GCCTACACCAAGATCGTGGAGAAGCTCTTCGAGCTCGACCCCGACGGCACCGTCATGGCG 343

Qy         62 CTGGCCGCGGTGCTGCGGGACAAGATCACCATGCCCGGCCAGCTCATGACCGACGGCCGC 121
              ||  |||   || || || | || ||| | ||||| |  || || |||   ||||||
Db        344 CTCTCCGACATGATGAGGAAGAAAATCTCAATGCCGGCACACCTGATGTTTGACGGCAAG 403

Qy        122 GACGCCGACTTGTTCGAGCACTTCTCGGCGGTCGCGCAGCGCACCGGGGTGTACACGGCA 181
              |||| | || | |||||||| ||||||  |    | || ||   ||| || ||||| ||
Db        404 GACGACAACCTTTTCGAGCATTTCTCGCGG---TCCCAACGGCTCGGAGTCTACACCGCG 460

Qy        182 AGAGACTACGGCGACATGGTGGAGCACTTCGTGCGTAGGTGGAAGGTGGCGGACCTCGGC 241
              || ||||||| ||||||  |||||  ||| ||   ||| ||||| ||||    | |||
Db        461 AGGGACTACGCCGACATATTGGAGTTCTTGGTCGCTAGATGGAACGTGGACAAGCTCACG 520

Qy        242 GGGGGGCAGCTGTCCGGGGAGGGGCGGCGCGCGCAGGAGTACGTGTGCGGGCTGCCGCGC 301
              ||        || |||||||| |||||  | ||||| || || |||||||||| || |||
Db        521 GG------TCTCTCCGGGGAAGGGCGTAGAGCGCAAGATTATGTGTGCGGGTTGGCGCAG 574

Qy        302 AAGATCCGGCGGGTGGAGGAGCTGGCCCACGACCGCGTGATCAAAGCCGCAAAAGAGCCC 361
              | ||||||| || |||||||||  || ||  |  | | ||   ||||  | |  |  ||
Db        575 AGGATCCGGAGGTTGGAGGAGCGAGCTCAGAAAAGAGCGAAGGAAGCAACGATGGTTCCT 634

Qy        362 GAGTTCGCAAGGTTCAGCTGGG 383
                  |   |  ||| |  |||
Db        635 TTCAGCTGGATCTTCGGGAGGG 656
```

14. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by NEB catalog (1998/1999), pp. 121, 284.

The specification defines a "substantially purified nucleic acid molecule" as a molecule separated from substantially all other molecules normally associated with it in its native state (page 15). Additionally, the specification teaches that nucleic acid molecules of the invention include the EST nucleic acid molecule of SEQ ID NO: 11 as well as fragments thereof. The specification teaches (page 14) that a fragment may comprise smaller oligonucleotides from about 15 to about 250 nucleotide residues and more preferably about 15 to about 30 nucleotide residues. The term "about" has not been defined. The recitation of "a nucleotide sequence" in

claims 1, 2, 4, and 5 encompasses sequences from within the recited SEQ ID NO: 11, including oligonucleotides as defined by the specification. The article "a", as defined by the art (see http://www.onelook.com/?w=a&ls=a) referred to as "the indefinite article, signifying one or any". This is contrasted to the word "the" which is defined by the Oxford English dictionary as the definite article, used to refer to a person place or thing that is unique (see http://www.askoxford.com/concise_oed/the?view=uk).

The NEB catalog offered for sale a random primer mix of 12mer and 24mer nucleotide primers. As the calculation below shows, about 3.2 x 10^8 molecules of every 12-mer and about 9 molecules of every single 24 mer are present in each tube of the 12 and 24 nucleotide mixtures respectively.

a. Molecular weight of 12-mer:

12 x 325 daltons/nucleotide = 3,900 daltons = 3,900 g/mol

b. Total number of possible 12-mers:

$4^{12} = 1.6 \times 10^7$ molecules

c. How many molecules of 12-mer in a vial sold by NEB:

1 A260 unit = 33 mg = 3.3×10^{-5} g

3.3×10^{-5} g □ 3,900 g/mol = 8.4×10^{-9} mol

$(8.4 \times 10^{-9}$ mol) x $(6.02 \times 10^{23}$ molecules/mol) = 5×10^{15} molecules

d. How many molecules of each 12-mer in a single vial:

5×10^{15} molecules □ 1.6×10^7 molecules = 3.2×10^8 molecules of each 12-mer per vial

e. Molecular weight of 24-mer:

24 x 325 daltons/nucleotide = 7,800 daltons = 7,800 g/mol

f. Total number of possible 24-mers:

$4^{24} = 2.8 \times 10^{14}$ molecules

g. How many molecules of 24-mer in a vial sold by NEB:

1 A260 unit = 33 mg = 3.3×10^{-5} g

3.3×10^{-5} g □ 7,800 g/mol = 4.2×10^{-9} mol

$(4.2 \times 10^{-9}$ mol) x $(6.02 \times 10^{23}$ molecules/mol) = 2.5×10^{15} molecules

h. How many molecules of each 24-mer in a single vial:

2.5×10^{15} molecules □ 2.8×10^{14} molecules = 9 molecules/vial

The claims encompass a very large genus of possible nucleic acids with no particular base composition or length. The NEB catalog vials will inherently and necessarily contain 12 and 24 nucleotides probes encompassed by the claimed recitation. As the specification has not defined the term "about", the claims have been given their broadest reasonable interpretation consistent with the teachings of the specification and the art. Claims 1, 2, 4, and 5 are not limited to sequences which are identical to SEQ ID NO: 11 or its' complement.
Note, regarding the previous rejections made over 4mer and 10mer nucleic acid molecules, as applicants stated on the record that claims 1-8 do not encompass 4 and 10 mer nucleotide sequences (see response dated 11/3/2006), the rejections have not been reinstated.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Jehanne Sitton/
Primary Examiner
Art Unit 1634
11/9/2007

/Ram R. Shukla/
Supervisory Patent Examiner
Art Unit 1634